REMARKS

35 U.S.C. §112, First Paragraph Rejection, Enabling

Claims 1-7 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. The rejection is traversed.

(a) The examiner states that it is essential that starting materials are provided.

A person skilled in the art knows what kind of starting materials are required for a particular purpose. For example, it is apparent that for assaying a chromosomal overrepresentacion within a tumor, tumor tissue has to be taken from a patient by biopsy. These cells can than be used for the process of claim 1 exactly following the instructions given in the example of the present application. At page 4 of the specification, it is stated that for the preparation of the interphase nuclei, known methods can be applied and corresponding publications are listed at the bottom of page 4. Thus, a skilled person should have no problem to select suitable starting materials.

(b) The examiner states that an additional reason why the claims are not enabled is that reaction conditions are not provided.

Detailed reaction conditions are given in the Example. Steps 1 –4 of the Example are not only suitable for the analysis of small cell populations of the cell line Colo 320 but also useful for the analysis of any kind of cells.

(c) The examiner sates that the specification is entirely silent as to how any disease would be diagnosed.

This analysis of the examiner apparently is based on the conclusion that the claims encompass the diagnosis of any DNA-based disease and in this context the examiner made reference to the specification on page 3, lines 4-9. However, this objection is without any basis since new claim 1 does not relate to a diagnostic method but merely relates to the detecting of chromosomal overrepresentation in cells. However, the specification is even enabling for the diagnosis because at

the priority date of the present application, the particular kinds of chromosomal overrepresentations that could be found in particular diseases were already known for a person skilled in the art. Therefore, for the diagnosis of particular diseases, a person skilled in the art merely has to compare the results obtained by the method of claim 1 with the chromosomal overrepresentations described for the particular diseases in the prior art. For example, if a skilled person found an overrepresentation of the chromosomal region 12ql2-q21, he could easily check the literature as to which diseases are characterized by such kind of chromosomal alterations.

(d) The examiner also states that it is unclear how any numerical change in any chromosome in any form would be detected.

There is no doubt that the instructions given in the example do not only apply to the particular cell line of the example, but also can be generally applied. By use of the universal PCR-Primers shown in Fig. 1 and referred to on page 2, 2nd full paragraph of the specification, particular regions of every chromosome can be amplified in principle. Accordingly, a person skilled in the art can detect the overrepresentation of any chromosome due to the application of these primers by assaying after step (d) of claim 1, whether the second label hybridizing to a particular chromosome has the same concentration as the first label, or whether the second label is overrepresented or underrepresented.

(e) Claim 3

The examiner states that Claim 3 requires the use and analysis of cells derived from the blood of a pregnant individual; such language fairly encompasses prenatal testing and the specification is essentially silent as to how to analyze fetal cells and how to make any useful determination therefrom.

This objection is again without any basis since Claim 3 does not necessarily relate to prenatal testing. It merely relates to a process for detecting chromosomal overrepresentation in cells wherein the cells are taken from the blood of pregnant persons. However, this process is in

deed suitable for prenatal testing, since it was already known before the priority date of the present application that even in the blood of pregnant persons, cells could be found showing the abnormalities of the fetus.

(f) The Examiner states that the specification is entirely silent as to how CGH method can be practiced with virtually any cell.

The Examiner's statement is not justified because at the end of Example 1, step 4, reference is made to the literature describing CGH method. Although, there is no detailed description of this method in the specification, it is apparent to a skilled person that the method can be applied to any cell, and not restricted to the particular cells mentioned in the literature referred to at the end of the specification.

For the Reasons stated above, the §112, first paragraph, enabling rejection of Claims 1-7 should be withdrawn.

35 U.S.C. §112, First Paragraph Rejection, Written Description

Claims 1-7 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement.

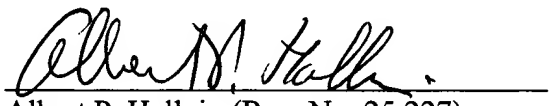
For the same Reasons stated above, the §112, first paragraph, enabling rejection of Claims 1-7 should be withdrawn.

CONCLUSION

It is now believed that the application is in condition for allowance and advancement as such is earnestly requested. Should any questions arise in connection with this submission which may be resolved by a telephonic interview, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

Date: March 12, 2004



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